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February 27, 2000

Dockets Management Branch
HFA-305, Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD, 20852

RE: Docket No: 00N-0001 "Leveraging collaboration with Stakeholders".

It was a pleasure to review the notice of the above mentioned meeting. I regret not to be in the opportunity to submit a request for a presentation at the Stanford meeting, due to other commitments at that time. I therefore take the liberty submitting my comments hereby.

In this announcement the FDA suggests to leverage expertise by focussing on the safety aspect of product development, whereas the efficacy aspects is not addressed. This is in harmony with product development according to the "Fast Track Approval" procedure.

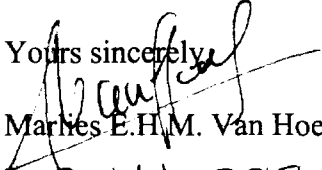
Regulatory allowance to focus primarily on safety and not on safety plus efficacy may result in registration of inferior products. Although registration of products based on inferior criteria may serve shareholders' wealth it will most likely not serve patient care neither health care economics.

The recommendation is therefore to focus leveraging both on safety and efficacy aspects of product development. The observation that deficiency in management and strategic product development planning rather than the quality of the product are reasons for failure of product development, should to my opinion not be emphasized by diminishing regulatory criteria.

Having shared these concerns, the procedure to be followed for safety assessment of products might benefit from similar procedures as might be followed for efficacy assessment. The author of this letter has dedicated ample consideration to appropriate product assessment including review, research and monitoring aspects and considers education an important means for user information.

The author would be delighted to discuss collaborating with FDA on these and other topics.

Yours sincerely,


Marië E.H.M. Van Hoef, MD, MBA.

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